EXHIBIT 61

[redacted]

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,	)	
Plaintiff,	)	
v.	)	
SAREPTA THERAPEUTICS, INC.,	)	
Defendant.	)	**C.A. No. 21-1015-GBW**
SAREPTA THERAPEUTICS, INC.,	)	
Defendant/Counter-Plaintiff,	)	
v.	)	
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC.	)	
Plaintiff and Counter-Defendants.	)	

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Wilmington, Delaware
Wednesday, May 3, 2023
Markman Transcript

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BEFORE: HONORABLE GREGORY B. WILLIAMS
UNITED STATES DISTRICT COURT JUDGE

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Michele L. Rolfe, RPR, CRR

APPEARANCES:

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-and-

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Attorneys for Defendant and Counter-Plaintiff Sarepta Therapeutics, Inc.

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PROCEEDINGS

(REPORTER'S NOTE: The following Markman was held in Courtroom 6B, beginning at 10:00 a.m.)

THE COURT: Good morning. You may be seated. All right. Let's start by having counsel put appearances on the record.

MS. DUDASH: Good morning, Your Honor. Amy Dudash from Morgan Lewis for plaintiff, Nippon Shinyaku. And with me here today is Amanda Williamson, Michael Sikera, Eric Kraeutler, Zachary Miller, Krista Venegas, as well as our client representative patent attorney from Nippon Shinyaku.

THE COURT: Good morning, all.

MS. DELLINGER: Good morning, Your Honor. Megan Dellinger of Morris Nichols of behalf of Sarepta and the University of Western Australia. And I'm joined this morning by my co-counsel from Finnegan Henderson, William Raich and Yoonjin Lee. And we also have with us this morning Mr. Mark Evans, who is in-house counsel at Sarepta.

THE COURT: All right. So we have a number of terms to construe today and we have two sets of briefs on the issues. We have -- we set aside three hours for this hearing. We'll start with the Wilton patents, so we'll start.

MR. RAICH: Thank you, Your Honor. We have printouts of our demonstratives, may we approach to deliver them?

THE COURT: Yes.

MR. RAICH: And, Your Honor, just by way of background, we've agreed to go term by term, so that's what we intend to do, unless you'd like something different.

THE COURT: No, term by term is typically how we do it.

MR. RAICH: Very good. Thank you. Bill Raich from Finnegan on behalf of defendant and counter-plaintiff Sarepta Therapeutics and The University of Western Australia.

So the Wilton patents disclose the pioneering work of Steve Wilton and colleagues at The University of Western Australia. It disclosed the first ever approved treatment for DMD and covered the first two FDA-approved treatments targeting exon 53. Sarepta's VYONDIS product, approved in 2019. And Nippon Shinyaku's VILTEPSO product approved the following year.

There are, as you know, three terms in dispute, shown with yellow, purple, and green highlighting on slide 3. And Nippon Shinyaku has identified three subterms that it believes should be separately construed.

And the disputed phrases work in unison to

structurally describe the claimed antisense oligonucleotide, thus construing them in the context of the claimed invention as a whole just makes sense.

That's also consistent with the Federal Circuit's guiding principal, the context of the surrounding words of the claim must be considered.

Indeed, Nippon Shinyaku understood how to read these terms in context. As mentioned, they have a product on the market that, just like Sarepta's, is directed to a target region of exon 53 of the human dystrophin pre-mRNA, and has all Ts, or thymines, instead of Us, or uracils.

And what you will see, Your Honor, is that by extracting terming that describe the claimed antisense oligonucleotide from the surrounding claim language, Nippon Shinyaku's constructions either impermissibly broaden the claims, as in the term "a base sequence," or make no sense, as in the context "annealling site." And as the Federal Circuit said, that's why Nippon Shinyaku's approach leads their constructions astray.

Now, Nippon Shinyaku asserts that five separate terms are indefinite. But NS has a high burden; it needs to prove indefiniteness by clear and convincing evidence.

It's also premature to evaluate indefiniteness, Your Honor. As courts in this circuit routinely refrain from reaching indefiniteness at this early stage of the

earlier, if we just look at the claim language, this is technical language so here's maybe an example. If you have something that says, for example, a Christmas tree comprising a trunk that is 100 percent wood, under their construction they would allow that trunk, if something was 50 percent wood and 50 percent plastic, something that was brought in a store, that would be okay, because part of it, 50 percent of it is 100 percent wood. That just doesn't make sense in this context in this art.

The base sequence refers to the base sequence of the oligonucleotide, that's how ever example was shown in the prior art, that's how the examples are in table 1A of the specification. That is consistent with how the term "base sequence" is used in this art.

I also want to talk about the specification and its warning. So as Sarepta's expert explained, under NS's construction, the antisense oligonucleotide could only have those 12 bases that I mentioned, which is -- if you have an oligonucleotide that's 31 nucleotides in length, that's less than 40 percent of the oligonucleotide that is complementary.

But the specification warns against using antisense oligonucleotides with insufficient complementarity to avoid nonspecific binding of antisense compounds to non-target secrets. So the specification guides that there

must be a sufficient degree of complementarity to avoid non-specific binding.

Their construction allows for very low levels of complementarity, but a skilled artisan is deemed to read the claim term not only in the context of the particular claim which the disputed term appears, but in the context of the entire patent, including the specification.

Now, NS suggests that an embodiment called a weasel supports its construction. This does not -- I just used the word "weasel" in the context of the case, this is a totally separate thing, so not to be confusing.

So the weasels are not encompassed by the asserted claims, and that's just fine. Patents are allowed to have alternative embodiments, some of which are encompassed by constructions and some of which are not. And we shouldn't contort the construction to try to reach something that's clearly not intended to be covered by the claims at issue.

So, first of all, the weasel is identified as three separate oligonucleotides, and the specifications says that you can join together multiple oligonucleotides to create a weasel, whereas the claim is drawn to "an antisense oligonucleotide." So that's the difference.

Separately, the weasel in the specification is 75 bases long, whereas the claim is drawn to something

that's 20 to 31 bases long.

The weasel targets intron sequence, whereas the claims are directed to targeting exon 53. So you put all of this together and the disclosure of the weasel is an unclaimed embodiment that is not relevant to the construction of these claims.

NS also looks to the prosecution history, and I want to address this briefly. So this is from the prosecution history of the Wilton patent. And the applicant was describing an oligonucleotide called H53A AON1, which it contended was a 18-mer oligonucleotide having a sequence identical to three nucleotides of SEQ ID NO: 195. That's all it says.

Now, NS contends that this defines the term "base sequence" in the claims, but this is not -- the claim term "base sequence," it just says a sequence. It's not discussing the claim term "base sequence." And it doesn't say that there are more than one base sequences in this 18-mer, it's simply saying that three nucleotides of the 18 are identical to another sequence.

So, further, if you look at the same response, NS ignores that applicant depicted the prior art oligonucleotide as having a single nucleotide sequence, a single base sequence that was 18 bases long. And explained that it had only three bases of SEQ ID NO: 195, not that it

has multiple bases in the same oligonucleotide.

So Sarepta's construction, should the judge choose to construe this term, should be adopted. It is supported by the claim language, including the 100 percent complementarity limitation. It's supported by the specification's embodiments and the expressed guidance, and it follows the common use in the art.

THE COURT: Ms. Williamson, a few questions for you to clarify some things.

So how does NS respond to Sarepta's position that there is always a one-to-one correlation between an antisense oligonucleotide and its base sequence?

MS. WILLIAMSON: So, Your Honor, we -- we just don't believe that is the case. So, first, just to give a little background, I will turn to slide 17 of our presentation, so this is something that counsel made quite a bit of argument about. The antisense oligonucleotide of 20 to 31 bases comprises a base sequence.

So we think that's very important because, first, comprising is open-ended, and second, because -- as Your Honor pointed out, because of the modification of the "a base sequence." It also has additional requirements in the claim, that base sequence comprises at least 12 consecutive bases of SEQ ID 195. We all agree to that.

So the minimum base sequence within the claim is

deprotecting agent. But, again, nothing in the claims or the specifications suggest that such indirect reactions are allowed, either under the plain claim language or the sole embodiment disclosed in the specification.

NS's counsel argue that somehow it is wrong that Sarepta's construction read out this method B. But respectfully, there's nothing that the come -- that NS's claim cannot cover method B under Sarepta's constructions. The claim says what it says, and the claims as written should be construed, as the Federal Circuit explained in the *Chef America*.

And for those reasons, Sarepta's construction should be adopted because it is based on the plain claim language and is also consistent with the intrinsic evidence, including the sole embodiment in the specification, and that's how the skilled artisan would have understood, as explained by Dr. Pentelute.

THE COURT: All right. I understand your argument.

MR. MILLER: Just a few very quick points, Your Honor. First, my opposing counsel mentioned the fact that the claims have lettered steps and numbered compounds, and argued that those letters and numbers imported a -- implied a step order.

Your Honor, respectively, those letters and

numbers are used for organizational purposes, so that in later dependent steps, instead of reciting the entire step, the dependent claim -- I'm sorry, in dependent claims, instead of reciting an entire step from the independent claim, the independent claim can simply identify step E as the one being further modified, or other steps like that.

And the same reason those numbered compounds are provided numbers, so you can use a shorthand instead of repeating the structure of each numbered compound every single time it's used, you can just recite to the earlier numbered structure.

I'd also like to pull up slide 21 from my opposing counsel's presentation. And I think this generally shows the improper way that -- that Sarepta has construed these claims. Sarepta is -- if you look at the claims themselves, they say "reacting said Compound 3. And reacting said Compound 4."

Instead of looking at that claim language, Sarepta is importing the underlined limitations from the specification, from an embodiment in the specification that Compound 3 must be produced in step B or produced in step C into the claims themselves.

And we already know that importing limitations from the specification, from an embodiment in the specification, even if it is the only embodiment in the

specification, that's improper. And for those reasons, NS's proposed construction should be adopted, Your Honor.

THE COURT: All right.

MR. MILLER: Thank you.

THE COURT: Thank you.

All right. The Court wants to thank counsel on both sides for your presentations today. The Court will take these matters under advisement and issue a *Markman* ruling as soon as it can. We've been trying to get them out within 60 days, so we will do our best in keep that up.

So with that, that's all I had on the agenda for the day for these parties, so with that we are adjourned.

(Whereupon, the following proceeding concluded at 1:13 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Michele L. Rolfe, RPR, CRR

U.S. District Court